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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,670	PETERSEN ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-12 and 44-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-12, and 44-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed January 29, 2008 have been fully considered but they are not persuasive.

The applicant has argued that Annis (EP 0 248 544 A1) teaches away from having a high water content. The examiner disagrees. Annis clearly states that a 95 percent weight water content is preferred (col.2, lines 51-52; col.3, lines 29-31). This is the same water content used by the applicant, see applicants specification on page 5, lines 15-27. Annis does not teach away from the high water content, since Annis clearly discloses use of the same water content as the applicant has disclosed. Applicant points to col.3, lines 1-3 and argues Annis teaches away from such a water content. The examiner disagrees. This statement is irrelevant as we have already established that Annis has met the claim language of a high water content. For the sake of responding to the applicants argument, this reference on col.3, lines 1-3 is referring to the ability to suture the device may prove difficult. Suturing is however not required, Annis discloses later that an adhesive may instead be used (col.4, lines 32-36). Whether suture or adhesive is used, the hydrogel still has a preferred 95 percent weight water content (col.2, lines 51-52).

Referring to the consisting essentially of language: it is noted that although Annis has shown use of a reinforcement (12), this is not mandatory (see abstract, wherein it is disclosed that the hydrogel may be homogeneous therethrough). The consisting essentially of language refers to the hydrogel anyhow, the reinforcements not being part of the hydrogel.

The applicant has also argued that Annis' device is rigid (this property related to the claimed viscosity). The examiner disagrees. Annis discloses lower water contents provide for

more rigid or stiff materials, thus the reason for the high (95%) water content, to provide less rigidity and more flexibility (col.2, lines 45-52), thus a viscosity similar to the applicants.

The applicant has also argued that MBA is at a molar ratio of over 10,000:1, this is under the assumption that MBA is 0.1% of the acrylamide content, which is not necessarily the case. The 0.1% would seem to the examiner to refer to the percent weight of the entire hydrogel (water included). Either way, the molar ratio is not disclosed by Annis, and being that it is unclear what ratio the components of Annis's hydrogel are present, it would be obvious to use routine experimentation to alter or tweak the components for the optimal properties.

The applicant repetitively argued that Annis's endoprosthesis is used for a different prosthetic role. The examiner disagrees. Both Annis and the applicant's prostheses are used for as a soft tissue implant, for placement inside the body. Further, applicant has only claimed, "for use as an endoprosthesis". First, the type of endoprosthesis or application is not specifically claimed. Second, this is intended use language and all that is required is that the hydrogel be capable of implantation in the body, which it is.

In summary, Annis is believed by the examiner to disclose a hydrogel having *all material components* claimed (water, acrylamide, methylene bis-acrylamide), the water having a high content the same as the applicants device (95 percent), therefore leaving the other components to have similar amounts and thus properties as claimed. Since exact amounts (of acrylamide and MBA) are not disclosed, it would have been obvious to modify the amount of components present in order to optimize the material properties of the composition for the desired application. As all implants in the medical field are in the same field of art.

The applicant has argued that Purkait (EP0 895 785 A2) does not disclose a hydrogel that is an endoprosthesis itself. The examiner disagrees. The hydrogel (although within a shell) is an endoprosthesis, as the hydrogel is placed within a human body. The claim does not exclude the use of an outer shell. Further, it is noted that the applicant uses a shell/envelope, see claim 46, so it is unclear how the two are different. All that is required by the claim is a hydrogel for use as an endoprosthesis, therefore, capable of being placed in the body. Purkait's hydrogel has this capability and meets the claim.

The applicant has also argued that Purkait's hydrogel is not bio-stable. The examiner disagrees. Purkait's hydrogel is within an envelope, thus is considered stable. Further, the compositions are so similar it would seem to be just as stable as the applicant's hydrogel.

The applicant has argued that Purkait's hydrogel contains three components, thus does not consist essentially of cross-linked acrylamide and water. The examiner disagrees. Referring to claim 1, the hydrogel is considered to be the cross-linked acrylamide composition ONLY-as this composition has capability of for implantation in the body separately, as it is a separate component before mixed with the other acrylamide. Referring to claims 51 and 51, the hydrogel is considered the entire three component composition and the polyacrylamide is considered only the cross-linked first component. The hydrogel in these claims does not consist essentially of; it is the acrylamide (first component) that consists essentially of. The first component of Purkait has the same materials claimed, in the same weight percentages claimed, with the viscosity claimed. The ratio is not disclosed nor the ppm or modulus. The composition of the first component of Purkait is VERY close to the applicants claimed hydrogel. It would have been obvious to have the ppm and ratio claimed, as this would require only routine experimentation to

optimize the properties (viscosity and modulus-viscosity which is already the same as claimed) for the desired application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 7-12, 45, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annis et al; National Research Development Corporation, (EP 0 248 544 A1, cited in IDS). Annis discloses a biostable hydrogel (col.2, lines 32-38) for use as an endoprosthesis (body 12 is implanted in the body, see fig.4) consisting essentially of a polymer of acrylamide cross-linked with methylene bis-acrylamide (col.3, lines 29-38) and water. Annis's hydrogel has a water content of 95 weight percent (col.2, lines 51-53; the same amount of water disclosed by applicant). Annis discloses a composition having the same material components claimed by the applicant. Although we know that the acrylamide and methylene bis-acrylamide of Annis is less than 4 percent by weight (since the water content is 95 percent and ammonium persulphate-also disclosed to be used by applicant-is 1 percent, leaving only 4 percent leftover), Annis is silent to mention the exact percent of acrylamide and methylene bis-acrylamide (MBA) and their ratio to one another. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio and amount of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component) of a claim

are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus and viscosity, since such as inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Claims 1, 2, 5, 7-12, 44-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait, Mentor Corporation (EP 0 895 785 A2, cited in IDS). Referring to the claim 1 grouping, Purkait discloses a biostable hydrogel (first component) for use as an endoprosthesis (has capability alone, as it is once a separate component) consisting essentially of polyacrylamide that includes acrylamide cross-linked with methylene bis-acrylamide (pg.7 line 55-56-pg.10, lines 32-34). Purkait's hydrogel has an acrylamide percent of 1-9 by weight (pg.7 lines 55-57; solid content of 2 percent, pg.10, lines 31-34) and the viscosity claimed (pg.10, lines 32-34, 15000-75000cps falls within claimed range). Purkait discloses a composition having the same monomers claimed by the applicant in the same weight percent and same viscosity, however Purkait is silent to mention the exact ratio of acrylamide to methylene bis-acrylamide (MBA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component and acrylamide having the claimed weight percentages and viscosity) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus, since such are inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Referring to claim 51 and 52 grouping, Purkait discloses a hydrogel (entire filling material in claim 1 and P0055) comprising a polyacrylamide (first component only) consisting essentially of acrylamide crosslinked with MBA (pg.6, line 58), wherein the hydrogel (entire filling material) comprises about 0.5 to 3.5 percent acrylamide by weight (disclosed to be 1-9 percents, so 1-3.5 falls within claimed range; pg.7, lines 55-56). Purkait discloses the hydrogel composition substantially as claimed (having the same water content and acrylamide content as applicant discloses; and claimed viscosity, pg.10, lines 32-34) however is silent to mention the exact ratio of acrylamide to methylene bis-acrylamide (MBA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component and acrylamide having the claimed weight percentages and claimed viscosity) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus, since such are inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait, Mentor Corporation (EP 0 895 785 A2, cited in IDS) in view of Vogel et al. (US 6,660,301 B1). Purkait discloses a polyacrylamide hydrogel for use as an endoprosthesis substantially as claimed (see above). Purkait does not however, disclose the use of cells on the endoprosthesis. Vogel teaches in the same field of polyacrylamide hydrogels, the use of a layer of cells on the endoprosthesis for the purpose of increased biocompatibility and attachment (col.6, lines 1-20; col.10, lines 30-

33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Vogel's teaching of using cells on polyacrylamide endoprostheses, with the polyacrylamide endoprosthesis of Purkait, in order to provide an endoprosthesis with increased biocompatibility and surface attachment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738